

**REMARKS**

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the remarks herewith.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 96-116 and 127-129 are currently pending. Claims 97-100, 103 and 127-129 have been amended, and new claims 130 and 131 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that the claims, as originally presented and as herein presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The claims presented herein, are not amended for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these claims are amended simply for clarification and to round out the scope of protection to which Applicants are entitled.

**II. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME**

The Office Action objected to the claims due to recitations of:

“relative homogeneity”;

“has an *in vivo* activity and an activity of at least 200,00 U/mg or of about 500,00 u/mg”;

“200,000 u/mg” or “500,000 u/mg”;

“desired”; and

“specific activity”.

Applicants respectfully submit that the term “relative homogeneity” is defined in Example 9. The use of the term in the claims is consistent with the use in the specification, such that no amendment should be necessary.

Applicants respectfully submit that the claims are directed to an erythropoietin that has: (i) *in vivo* activity; **and** (ii) an activity of at least 200,000U/mg protein or of about 500,000 U/mg protein. The claims have been amended to ensure that this is clear.

Applicants respectfully submit that the remaining objections are also rendered moot by the amendments herein. Consequently, reconsideration and withdrawal of the objections to the claims is respectfully requested.

## **II. THE ART REJECTIONS ARE OVERCOME**

Claims 96-97, 99-116 and 127-129 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Quelle *et al.* with evidence provided by Dorland's Illustrated Medical Dictionary and claims 96-116 and 127-129 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Quelle *et al.* with evidence provided by Dorland's Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). It is also well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The claims as amended herein now clearly describe an erythropoietin having two separate activities: (i) an in vivo activity; and (ii) an in vitro activity of at least 200,000 U/mg. Nothing in Quelle *et al.* provides for the existence of both of the claimed activities.

Therefore, because Quelle *et al.* does not contain all the elements of the presently claimed invention, and because Quelle *et al.*, either alone or in combination with any other reference, does not provide any teaching, suggestion, motivation, or incentive to modify to allow one of

skill in the art to arrive at the present invention, it is respectfully requested that the rejections under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

The remarks herein place the application in condition for allowance. An early and favorable consideration of the application on the merits, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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